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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/662,441

09/16/2003

Finn Myhren

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EXAMINER

BADIO, BARBARA P

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

11/18/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/662,441	Applicant(s) MYHREN ET AL.	
	Examiner Barbara P. Badio	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57, 70, 71 and 88 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 57, 70, 71 and 88 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 8, 2010 has been entered.

Status of the Application

2. Claims 57, 70, 71, and 88 are pending in the present application. The instant claims stand rejected as indicated below.

Claim Rejections - 35 USC § 103

3. The rejection of claims 57, 70, 71 and 88 under 35 USC 103(a) over Favre et al. (US 5,324,821) is maintained.

Applicant argues (a) the instant claims are to specific fatty acids, (b) Favre discloses the use of "saturated or unsaturated fatty acids having 4 to 24" carbon atoms and not all members of the genus would be expected to have similar properties, (c) there is nothing of record that would rationally explain why one of skill would choose the specifically claimed fatty acids and (d) Favre does not teach or disclose any type of

therapeutic effect of the compounds disclosed therein. Applicant's argument was considered but not persuasive for the following reasons.

The issue is not the specificity of the claimed fatty acids. The issue is the obviousness of the claimed invention based on the utilization of fatty acids in combination with an anticancer agent as taught by Favre at the time of the present invention.

Favre centers on the use of modified lipoproteins to enhance the therapeutic efficacy of lipophilic active substances, i.e., to improve the delivery of lipophilic active substances to the target organ/cell. Amongst the lipophilic active substances taught by Favre are antineoplastic agents and the reference exemplifies a few including mitoxantrone and methotrexate. Favre also teaches that where the drug is not sufficiently lipophilic to be incorporated spontaneously into the lipid phase of the emulsion, chemical modification can be made such as by grafting said drug to fatty acids having 4 to 24 carbon atoms such as oleic acid.

Applicant argues the differences in the properties of genus of fatty acids taught by Favre and that there is nothing on record to explain why one of skill would choose the specifically claimed fatty acids.

The skilled artisan in the art would not expect the fatty acids to have identical properties. However, based on the teachings of Favre, one would have the reasonable expectation that any of the fatty acids of Favre would improve the lipophilic property of the active agent. Thus, the reason to choose the claimed fatty acids is the same reason to choose any of the fatty acids of the genus taught by Favre, i.e., to improve the

lipophilic property of the drug. Applicant has not provided any reason(s) why one of skilled in the art would not utilize each and every fatty acid encompassed by the prior art genus and/or why the use of the claimed fatty acids would not be obvious based on the teachings of Favre.

Lastly, it is noted that the other anticancer agents recited by the instant claims are well known anticancer agents (see for example, US 5,160,727, col. 3, lines 32-45; US 5,874,481, col. 12, lines 49-50).

In summary, Favre teaches chemical modification of lipophilic drugs such as anticancer agents to improve their lipophilic property and, thus, their incorporation into lipoproteins in order to enhance their efficacy. The instantly claimed anticancer agents are well known in the art and, thus, modification of the claimed compounds as encompassed by the instant invention is made obvious by the teachings of Favre. Applicant has not provided any evidence on record showing the unobviousness of the claimed fatty acids over others taught by Favre.

For these reasons and those given in the previous Office Action, the rejection of claims 57, 70, 71 and 88 under 35 USC 103(a) over Favre et al. (US 5,324,821) is maintained.

Telephone Inquiry

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Barbara P. Badio/
Primary Examiner, Art Unit 1628